

REMARKS

In this Amendment, Applicant has cancelled Claims 1 – 18 and 22 – 25 to delete the non-elected invention. Applicant reserve the right to file divisional applications directed to these inventions. In addition, Claims 19 – 20 have been amended and Claims 26 – 28 have been added to overcome the rejections and further specify the embodiments of the present invention. Moreover, the specification has been amended to overcome certain informalities. It is respectfully submitted that no new matter has been introduced by the amended claims and specification. All claims are now present for examination and favorable reconsideration is respectfully requested in view of the preceding amendments and the following comments.

REJECTIONS TO THE SPECIFICATION:

The specification has been objected as failing to provide proper antecedent basis for the claimed subject matter. It is respectfully submitted that the objection has been overcome by the current amendment. The contents of Claims 20 and 21 have been added into the specification. Therefore, there is sufficient support for the claimed subject matter and no new matter has been introduced by the amendment.

REJECTIONS UNDER 35 U.S.C. § 112 FIRST PARAPGRAPH:

Claims 19 – 21 have been rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to satisfy the enablement requirement and contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

It is respectfully submitted that the rejection is incorrect because the specification sufficiently describes the present invention and enables a person of ordinary skill in the art to practice the claimed invention without undue experimentation. According to MPEP 2164.01(a), there are many factors to be considered when determining whether there is

sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue." These factors include, but are not limited to:

- (A) The breadth of the claims;
- (B) The nature of the invention;
- (C) The state of the prior art;
- (D) The level of one of ordinary skill;
- (E) The level of predictability in the art;
- (F) The amount of direction provided by the inventor;
- (G) The existence of working examples; and
- (H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)

The examiner's analysis must consider all the evidence related to each of these factors, and any conclusion of nonenablement must be based on the evidence as a whole. 858 F.2d at 737, 740, 8 USPQ2d at 1404, 1407. In addition, according to MPEP 2164.01(b), as long as the specification discloses at least one method for making and using the claimed invention that bears a reasonable correlation to the entire scope of the claim, then the enablement requirement of 35 U.S.C. § 112 is satisfied. *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). Failure to disclose other methods by which the claimed invention may be made does not render a claim invalid under 35 U.S.C. § 112. *Spectra-Physics, Inc. v. Coherent, Inc.*, 827 F.2d 1524, 1533, 3 USPQ2d 1737, 1743 (Fed. Cir.), *cert. denied*, 484 U.S. 954 (1987). Furthermore, under MPEP 2164.02, a single working example in the specification for a claimed invention is enough to preclude a rejection which states that nothing is enabled since at least that embodiment would be enabled. The presence of only one working example should never be the sole reason for rejecting claims as being broader than the enabling disclosure, even though it is a factor to be considered along with all the other factors. To make a valid rejection, one must evaluate all the facts and evidence and state why one would not expect to be able to extrapolate that one example across the entire scope of the claims.

It is respectfully submitted that the references cited by the Examiner support the fact that the claimed two-step cloning process can be successfully practiced by a person of ordinary skill in the art based on the disclosure of the present application and the knowledge of the person of ordinary skill in the relevant art. For example, both

Wakayama and Hochedliger failed to succeed with first generation cloning, but Hochedliger was successful when it introduced the step of preparing a second-generation embryo. The Examiner has not taken into consideration the evidence from these references supporting the enablement of the present invention as required by the MPEP. In addition, the present application includes a working example of the claimed two-step cloning method. The actual example is sufficiently clear to a person of ordinary skill in the art to carry out the invention as claimed. The Examiner has not considered such actual example as a factor as required by the MPEP.

Furthermore, the Examiner suggested the unpredictability nature of the second generation cloning technique. However, Applicant respectfully submits that the disclosure of the present application and the references cited by the Examiner indicate that introducing a step that leads to the formation of a second generation embryo increases the chances of success to the point that live and healthy cloned mammals have actually been born.

Moreover, Applicant respectfully disagrees with the Examiner's suggestion that precisely optimizing the size of the pipette and using a piezostepper to rupture the oocyte membrane are essential steps. Not only is it not essential to rupture the cell membrane (see page 3, second paragraph of the specification of the present application, which discusses "optionally" breaking the cell membrane), but there are also many ways to break the cell membrane, other than using a piezostepper. The fact that scientists chose to use this method of rupturing the cell membrane in a paper published after the filing date of the present application simply highlights one way in which this step, if used, can be carried out.

On page 4 of the Office Action, the Examiner alleges that "Claims 19 – 21 are not enabled because at the time of filing, the art regarded the production of nonprimate mammals by nuclear transfer are not enabled." Applicant respectfully points out that the present application includes an actual example in which the birth of a non-primate (calf) was successfully achieved using the claimed two-step method. Considering the cost and time involved in carrying out these cloning methods, Applicant believes that it is entirely

unreasonable for the Examiner to expect the Applicant to provide efficacy data for all types of mammals. Under MPEP 2164.01, the fact that experimentation may be complex does not necessarily make it undue, if the art typically engages in such experimentation. *In re Certain Limited-Charge Cell Culture Microcarriers*, 221 USPQ 1165, 1174 (Int'l Trade Comm'n 1983), *aff'd. sub nom., Massachusetts Institute of Technology v. A.B. Fortia*, 774 F.2d 1104, 227 USPQ 428 (Fed. Cir. 1985). In addition, the specification provided detailed specific guidance to enable a person of ordinary skill in the art to practice the invention.

It is respectfully submitted that the present invention provides a method of cloning animals from lymphocytes as opposed cells obtained from a mammalian pre-implantation embryo. This has the advantage of enabling cloned mammals to be formed from abundant lymphocytes, as opposed to have to use the much less abundant cells from mammalian pre-implantation embryos. With the support of the actual example and the success in the prior art, including those in the cited references, Applicant has provided sufficient disclosure that enable a person of ordinary skill in the art to practice the invention.

Therefore, the rejection under 35 U.S.C. § 112, first paragraph has been overcome. Accordingly, withdrawal of the rejections under 35 U.S.C. § 112, first paragraph, is respectfully requested.

REJECTIONS UNDER 35 U.S.C. § 112 SECOND PARAPGRAPH:

Claims 19 – 21 have been rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is respectfully submitted that the rejections have been overcome by this amendment. More specifically, Claims 19 – 20 have been amended to add the steps identified by the Examiner. Claims 21 and 26 – 28 also include these steps by their dependency on Claims 19 – 20.

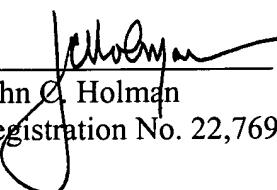
Therefore, the rejection under 35 U.S.C. § 112, second paragraph, has been overcome. Accordingly, withdrawal of the rejections under 35 U.S.C. § 112, second paragraph, is respectfully requested.

Having overcome all outstanding grounds of rejection, the application is now in condition for allowance, and prompt action toward that end is respectfully solicited.

Respectfully submitted,

JACOBSON HOLMAN PLLC

Date: September 20, 2006
(202) 638-6666
400 Seventh Street, N.W.
Washington, D.C. 20004
Atty. Dkt. No.: P66004US0

By 
John C. Holman
Registration No. 22,769